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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,016

01/23/2004

David Fikstad

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08/10/2006

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EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/764,016

Applicant(s)

FIKSTAD ET AL.

Examiner

Leslie A. Royds

Art Unit

1614

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1-36.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s): \_\_\_\_\_.  
13. ☒ Other: Ear Int. Sum. attachment

Leslie A. Royds  
Patent Examiner  
Art Unit 1614

04 AUGUST  
2006

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claims 8-12 and 13-15, 17-18 and 30 under 35 U.S.C. 112, second paragraph, and the obviousness-type double patenting rejection of claims 1-36 over US Patent Application 11/122,788.

Continuation of 11. does NOT place the application in condition for allowance because: This is to advise that the present advisory action supercedes the advisory action dated July 13, 2006, upon reconsideration of the amendments and declaration submitted under 37 C.F.R. 1.131, and further in light of the discussion held during the interview of 03 August 2006.

Applicant's after-final amendment proposes amending claim 8 to remove the limitation "a dissolving salt of a complex"; amending claims 13-15, 17-18 and 30 to clarify the associated numerical ranges; and amending the priority information at page 1 of the specification. Applicant's submission of a Terminal Disclaimer over U.S. Patent Application No. 11/122,788 and the declaration submitted under 37 C.F.R. 1.131 have each also been noted and considered.


Accordingly, Applicant's after-final amendment overcomes the rejection of claims 8-12 and 13-15, 17-18 and 30 under 35 U.S.C. 112, second paragraph, and the obviousness-type double patenting rejection of claims 1-36 over U.S. Patent Application No. 11/122,788.

It is further noted that Applicant's submission of the declaration under 37 C.F.R. 1.131 is a proper submission to overcome the present prior art rejection of claims 1-36 over the U.S. Patent to Patel ('192) as set forth under 35 U.S.C. 102(e). However, Applicant's statements and evidence made of record is insufficient to demonstrate that the entire scope of the claimed subject matter was conceived and reduced to practice prior to that of the '192 patent reference. In particular, it is noted that the declaration under 37 C.F.R. 1.131 is directed to a discrete combination of itraconazole, glycofurol, Tween-20, phosphoric acid, ethanol, sodium taurocholate and polyvinylpyrrolidone, which is but a very small scope of evidence as compared to the breadth of what is claimed in the Patel ('192) patent reference. In light of such, while the declaration is again noted to be an appropriate submission in order to overcome the 102(e) prior art rejection, the evidence demonstrated in the declaration is, respectfully, insufficient to establish on the record that Applicant had conceived and reduced to practice the entire scope of what is presently claimed as compared to the invention claimed by Patel.

As a result, the '192 patent remains prior art over the presently claimed subject matter and is properly applied under 35 U.S.C. 102(e).

Applicant's request at page 11 of the remarks that the provisional statutory double patenting rejection be held in abeyance until the claims of the present application have been finalized and allowed has been considered, but is not persuasive because the claims are not in condition for allowance since Applicant has failed to overcome the prior art rejection(s). For this reason, the provisional statutory double patenting rejection remains proper and is maintained for the reasons already set forth in the final rejection.

For the above reasons, the amendments, Terminal Disclaimer and declaration under 37 C.F.R. 1.131 will be entered into the record and the reply is noted to have overcome the rejections set forth under 35 U.S.C. 112, second paragraph, and the judicially created doctrine of obviousness-type double patenting. However, insofar as the reply fails to overcome both the prior art rejections set forth under 35 U.S.C. 102 and 35 U.S.C. 103 or the provisional statutory double patenting rejection, the claims remain rejected for the reasons previously made of record and set forth in the final rejection of April 20, 2006.

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER